JUL 2 4 2002

K 021499

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SPONSOR:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

MANUFACTURER:

DePuy International Ltd
Trading as DePuy CMW
Cornford Road
Blackpool, Lancashire
FY 4 4QQ, England

510(K) CONTACT:

Janet Johnson, RAC
DePuy Orthopaedics, Inc.
Group Leader, Regulatory Submissions
(574) 371-4907; FAX (574) 371-4987
E-mail: jjohnso7@dpyus.jnj.com

TRADE NAME:

CEMVAC Ultra Pre-packed with DePuy 1 Bone Cement

COMMON NAME:

Pre-packed Bone Cement Dispenser

CLASSIFICATION:

Cement Dispenser, Class I Exempt per 21 CFR 888.4200
PMMA Bone Cement: Class II per 21 CFR 888.3027

DEVICE CODE:

KIH pre-packed with LOD

EQUIVALENT DEVICES:

DePuy 1 Bone Cement – P960001/Supplement 3
Cemex System Gun Application Version – K000943
Howmedica Surgical Simplex P Radiopaque Bone Cement Pre-Packed in ACM and Mix Evac II – K002652

DEVICE DESCRIPTION AND INTENDED USE:

CEMVAC Ultra pre-packed with DePuy 1 Bone Cement is a in-syringe vacuum mixing system pre-packed with bone cement powder. The subject device is for single use and helps control monomer fumes during the preparation of the cement. The subject device pre-packed with DePuy 1 Bone Cement is available in a single 60g or 100g unit and also in unit packs of 5. Each single unit (device) pack consists of 1) syringe barrel filled with bone cement powder; 2) central mixing rod; 3) locking plate; 4) filter/vacuum hose; 5) vacuum pump adapter; 6) monomer cartridge with glass ampoules containing bone cement liquid; and 7) plastic disposal bag.

CEMVAC Ultra pre-packed with DePuy 1 Bone Cement is indicated for the fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty.

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BASIS OF SUBSTANTIAL EQUIVALENCE:

With the exception of the primary packaging of the powder component of the DePuy 1 Bone Cement in the CEMVAC Ultra device, the DePuy 1 Bone Cement is identical in materials (formulation), and indications for use as the currently marketed DePuy 1 Bone Cement. On testing, DePuy 1 Bone Cement powder has been found to be compatible and stable in the CEMVAC Ultra device. Comparable DePuy 1 Bone Cement compressive, flexural and impact strengths were obtained for bowl and spatula and CEMVAC Ultra mixed cements.

CEMVAC Ultra pre-packed with DePuy 1 Bone Cement has similar indications for use as other bone cements currently marketed in the United States. These predicate devices include:

1) Cemex System Gun Application Version marketed by Tecres,
2) Howmedica Surgical Simplex P Radiopaque Cement Pre-Packed in ACM or Mix Evac II marketed by Stryker Corporation.

All three pre-filled mixing systems are pre-packed with bone cement and are intended to be used for the fixation of artificial joints prostheses to host bone.

Based on similarities of design, materials, intended use, and testing, DePuy believes that the CEMVAC Ultra pre-packed with DePuy 1 Bone Cement is substantially equivalent to the Cemex System Gun Application Version by Tecres, Howmedica Surgical Simplex P Radiopaque Cement Pre-Packed in ACM or Mix Evac II marketed by Stryker Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 4 2002

Ms. Janet G. Johnson, RAC
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 4681-0988

Re: K021499
Trade Name: CEMVAC Ultra Pre-packed with DePuy 1 Bone Cement
Regulation Number: 21 CRF 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD
Dated: May 8, 2002
Received: May 9, 2002

Dear Ms Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number (if known): K021499

Device Name: CEMVAC Ultra Pre-packed with DePuy 1 Bone Cement

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Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021499

Prescription Use_X__ OR Over-The-Counter Use _____ (Per 21 CFR 801.109)